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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,202	01/03/2000	JOHN D. NOTI	052544-0108	7459

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MARK A KASSEK  
FOLEY & LARDNER  
P O BOX 1497  
MADISON, WI 537011497

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/476,202	NOTI, JOHN D.
	Examiner	Art Unit
	Konstantina Katcheves	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Claims 1-43 are pending in the present application.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 17, drawn to a promoter of CD11d gene, classified in class 536, subclass 24.1.
- II. Claims 7-16 and 43, drawn to a cis-acting element that influences the activity of a myeloid cell specific promoter, classified in class 536, subclass 24.1.
- III. Claims 18-31 and 32-39, drawn to a construct comprising a cell specific CD11d promoter and heterologous gene and a cell expressing said gene, classified in class 435, subclass 23.1.
- IV. Claims 40 and 41, drawn to a method of expression for myeloid cell specific genes, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

Each of inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to chemically and functionally distinct products and a distinct method such that restriction is proper. Group I is unrelated to Group II because each is a different product with different functions. The promoter of Group I may be used for various purposes and in concert with any desired gene. Group II is a cis-acting element that

either inhibits or enhances the activity of the promoter of Group I. The product of Group II is not a promoter like Group I and clearly has a different function. The cis-acting element modulates the activity of a promoter. Moreover, the product of Group III is drawn to a construct comprising a promoter and gene of interest, which differs from the cis-acting element and the promoters in that it comprises a nucleic acid construct for the purposes of expressing a gene of interest in a cell. As such, the construct Group III differs from either products of Groups I and II. The distinct products of Groups I, II and III are different from the method of Group IV. The myeloid specific gene may be expressed using various promoters and vector constructs such that the products of Groups I, II and III are not necessary for the practice of method on expressing myeloid specific genes.

Because these inventions are distinct for the reasons given above and the search required for any of the above groups is not required for any one of the others, restriction for examination purposes as indicated is proper. Moreover, the above groups have acquired a separate status in the art as shown by their different classification such that restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
June 21, 2002

*Remy Yucel*  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600